

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee (ALSDAC)
and Drug Safety & Risk Management Advisory Committee (DSaRM)

Holiday Inn, The Ballrooms, Two Montgomery Village Avenue, Gaithersburg, MD

AGENDA

September 24, 2009

The committees will discuss the resubmission of new drug application 22-272, OxyContin (oxycodone hydrochloride controlled-release) Tablets, Purdue Pharma L.P., and its safety for the proposed indication of management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. The controlled-release characteristics of this formulation are purportedly less easily defeated than other approved formulations of controlled-release oxycodone.

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| 9:15 a.m. | Call to Order Introduction of Committee | Jeffrey R. Kirsch, M.D. Acting Chair, ALSDAC |
| | Conflict of Interest Statement | Kalyani Bhatt Designated Federal Officer, ALSDAC |
| 9:25 a.m. | Opening Remarks | Ellen Fields, M.D., M.P.H. Clinical Team Leader Division of Anesthesia, Analgesia, & Rheumatology Products, CDER/FDA |
| 9:30 a.m. | History of OxyContin | Angelina Pokrovnichka, M.D. Medical Officer Division of Anesthesia, Analgesia & Rheumatology Products, CDER/FDA |
| 9:50 a.m. | Epidemiological Findings of Drug Misuse/Abuse In the United States: OxyContin | Catherine Dormitzer, Ph.D., M.P.H. Epidemiologist Division of Epidemiology Office of Surveillance and Epidemiology CDER/FDA |
| 10:10 a.m. | Break | |
| 10:25 a.m. | Sponsor Presentations | Purdue Pharma L.P. |
| | Introduction | John Stewart Purdue President and Chief Executive Officer |
| | | Craig Landau, MD Purdue Chief Medical Officer, VP Clinical, Medical and Regulatory Affairs |

Sponsor Presentations (continued)

Purdue Pharma L.P.

Polyethylene Oxide Excipient

Craig Landau, MD

Purdue Chief Medical Officer,
VP Clinical, Medical and Regulatory Affairs

Bioequivalence

Stephen Harris, MD

Purdue Executive Director of
Clinical Pharmacology

Approach to In Vitro Testing

Edward Cone, PhD

Adjunct Professor of Psychiatry
Johns Hopkins University

In Vitro Testing Results

Craig Landau, MD

Purdue Chief Medical Officer,
VP Clinical, Medical and Regulatory Affairs

Judy Lee, PhD

Purdue Senior Director,
Analytics/Preformulation

Jennifer Giordano

Purdue Senior Research
Scientist Analytics

Interpretation of In Vitro findings

Dr. Edward Sellers, MD, PhD

Professor Emeritus of Pharmacology, Medicine
and Psychiatry,
University of Toronto

**Conclusions and Benefit Risk
Profile of Reformulation**

Craig Landau, MD

Purdue Chief Medical Officer,
VP Clinical, Medical and Regulatory Affairs

12:00 a.m. Lunch

1:00 p.m. Open Public Hearing

2:00 p.m. Questions for the Presenters

2:15 p.m. Break

2:30 p.m. Discussion and Questions to the Committee

4:30 p.m. Adjourn